FEIBA NF- anti-inhibitor coagulant complex
Baxter Healthcare Corporation

FEIBA NF (Anti-inhibitor Coagulant Complex)

Nanofiltered and Vapor Heated

Lyophilized powder for solution

Intravenous

WARNING

Thrombotic and thromboembolic events have been reported during postmarketing surveillance following infusion of FEIBA VH or FEIBA NF, particularly following the administration of high doses and/or in patients with thrombotic risk factors (See WARNINGS, PRECAUTIONS and ADVERSE REACTIONS).

DESCRIPTION

FEIBA NF (Anti-Inhibitor Coagulant Complex), nanofiltered and vapor heated, is a freeze-dried sterile human plasma fraction with Factor VIII inhibitor bypassing activity. *In vitro*, FEIBA NF shortens the activated partial thromboplastin time (APTT) of plasma containing Factor VIII inhibitor. Factor VIII inhibitor bypassing activity is expressed in arbitrary units. One unit of activity is defined as that amount of FEIBA NF that shortens the APTT of a high titer Factor VIII inhibitor reference plasma to 50% of the blank value.

FEIBA NF contains Factors II, IX, and X, mainly non-activated, and Factor VII mainly in the activated form. The product contains approximately equal unitages of Factor VIII inhibitor bypassing activity and Prothrombin Complex Factors. In addition, 1–6 units of Factor VIII coagulant antigen (FVIII C:Ag) per mL are present. The preparation contains only traces of factors of the kinin generating system. It contains no heparin.

Reconstituted FEIBA NF contains 4 mg of trisodium citrate and 8 mg of sodium chloride per mL.

FEIBA NF is manufactured from large plasma pools of human plasma. Screening against potentially infectious agents begins with the donor selection process and continues throughout plasma collection and plasma preparation. Each individual plasma donation used in the manufacture of FEIBA NF is collected only at FDA approved blood establishments and is tested by FDA licensed serological tests for Hepatitis B Surface Antigen (HBsAg), and for antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2) and Hepatitis C Virus (HCV) in accordance with the U.S. regulatory requirements. As an additional safety measure, mini-pools of the plasma are tested for the presence of HIV-1 and HCV by FDA licensed Nucleic Acid Testing (NAT) and found negative. In addition, two dedicated and independent virus removal/inactivation steps have been integrated into the manufacturing process, namely 35 nm nanofiltration and a vapor heat treatment process. In addition, the DEAE-Sephadex adsorption contributes to the virus safety profile of FEIBA NF. Despite these measures, such products can still potentially transmit disease (see *WARNINGS*).

In vitro spiking studies have been used to validate the capability of the manufacturing process to remove and inactivate viruses. To establish the minimum applicable virus clearance capacity of the manufacturing process, these virus clearance studies were performed under extreme conditions (e.g. at minimum incubation times and temperatures below specifications for vapor-heat treatment). Virus clearance studies for FEIBA NF performed in accordance with good laboratory practices have demonstrated, that the manufacturing process of FEIBA NF ensures a high margin of safety with respect

to adventitious viruses (Table 1).

Table 1: Mean log_{10} Reduction Factors (RFs) For Each Virus and Manufacturing Step

Virus Type	Enveloped RNA			Enveloped DNA	Non-enveloped RNA	Non-enveloped DNA	
Virus Family	Retroviridae	Flaviviridae		Herpesviridae	Picornaviridae	Parvoviridae	
Virus*	HIV-1	BVDV	WNV	PRV	HAV	B19V†	MMV
DEAE Sephadex Adsorption	3.2	1.8	n.d.	2.5	1.5	1.7	1.2
35 nm Nanofiltration	> 5.3	2.1	4.7	> 5.7	2.6	0.2‡	1.0
Vapor-Heat Treatment	> 5.9	> 5.6	> 8.1	> 6.7	> 5.2	3.5	0.9‡
Overall log reduction factor (ORF)	> 14.4	> 9.5	> 12.8	> 14.9	> 9.3	5.2	2.2

* Abbreviations: HIV-1, Human Immunodeficiency Virus Type 1; BVDV, Bovine Viral Diarrhea Virus (model for Hepatitis C Virus and other lipid enveloped RNA viruses); WNV, West Nile Virus; PRV, Pseudo rabies Virus (model for lipid enveloped DNA viruses, including Hepatitis B Virus); HAV, Hepatitis A Virus; MMV, Mice Minute Virus (model for non-lipid enveloped DNA viruses, including B19 virus [B19V]).

† Reduction factor for Parvovirus B19 claimed for the Vapor Heat Treatment is based on results derived from experimental infectivity and titration assays.

‡ Reduction factors < 1 log are not used for calculation of the overall reduction factor; n.d. (not done).

CLINICAL STUDIES

FEIBA NF is identical in formulation to FEIBA VH. Biochemical and preclinical studies have confirmed the comparability of FEIBA NF and FEIBA VH.

The safety and efficacy of FEIBA has been demonstrated by two prospective clinical trials[1,2]. The first, conducted by Sixma and collaborators, was a randomized double-blind study comparing the effect of FEIBA and PROTHROMPLEX IMMUNO (a non-activated prothrombin complex concentrate) in 15 patients with hemophilia A and inhibitors to Factor VIII. A total of 150 bleeding episodes (primarily joint and musculoskeletal plus a few mucocutaneous) were treated. A single dose of 88 Units per kg of body weight was used uniformly for treatments with FEIBA. The study showed that, based on subjective patient evaluation, FEIBA was fully effective in 41.0% and partly effective in 24.6% of episodes (i.e. combined effectiveness of 65.6%), while PROTHROMPLEX IMMUNO was rated fully effective in 25.0% and partly effective in 21.4% of episodes (i.e. combined effectiveness of 46.4%).

The second study with FEIBA was a multicenter study conducted by Hilgartner *et al*[2]. This study was conducted in 44 hemophilia A subjects with inhibitors, 3 hemophilia B subjects with inhibitors and 2 acquired FVIII inhibitor subjects. It was designed to evaluate the efficacy of FEIBA in the treatment of joint, mucous membrane, musculocutaneous and emergency bleeding episodes such as central nervous system hemorrhages and surgical bleedings. In 49 patients with inhibitor titers of greater than 5 Bethesda Units (from nine co-operating hemophilia centers), 489 single doses were given for the treatment of 165 bleeding episodes. The usual dosage was 50 Units per kg of body weight, repeated at 12-hour intervals (6-hour intervals in mucous membrane bleedings), if necessary. Bleeding was controlled in 153 episodes (93%). In 130 (78%) of the episodes, hemostasis was achieved with one or

more infusions within 36 hours. Of these, 36% were controlled with one infusion within 12 hours. An additional 14% of episodes responded after more than 36 hours.

Of the 489 single doses, only 18 (3.7%) caused minor transient reactions in recipients. Out of 49 patients, 10 (20%) showed a rise in their inhibitor titers. In 5 of these patients (10%), the rise was tenfold or more. However, of these 10 patients, 3 had received Factor VIII or Factor IX concentrates within 2 weeks prior to treatment with FEIBA. These anamnestic rises have not been observed to interfere with the efficacy of FEIBA.

INDICATIONS AND USAGE

FEIBA NF (Anti-Inhibitor Coagulant Complex) is indicated for the control of spontaneous bleeding episodes or to cover surgical interventions in hemophilia A and hemophilia B patients with inhibitors.

Clinical experience suggests that patients with a Factor VIII inhibitor titer of less than 5 B.U. may be successfully treated with Antihemophilic Factor. Patients with titers ranging between 5 and 10 B.U. may either be treated with Antihemophilic Factor or FEIBA NF. Cases with Factor VIII inhibitor titers greater than 10 B.U. have generally been refractory to treatment with Antihemophilic Factor.

Guidelines to First and Second Choice Treatment

Patient's Inhibitor	Clinical Situation		
Titer	Minor Bleeding	Major Bleeding	Surgery (Emergency)
less than 5 B.U.	AHF*	AHF	AHF
5 to 10 B.U.	AHF	AHF	AHF
	FEIBA NF	FEIBA NF	FEIBA NF
more than 10 B.U.	FEIBA NF	FEIBA NF	FEIBA NF

* AHF = Antihemophilic Factor

Inadequate response to treatment may result from an abnormal platelet count or impaired platelet function[3-5] that were present before treatment with FEIBA NF, nanofiltered and vapor-heated.

CONTRAINDICATIONS

The use of FEIBA NF is contraindicated:

- in patients who are known to have a normal coagulation mechanism.
- for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.
- in patients with significant signs of disseminated intravascular coagulation (DIC).

WARNINGS

Anaphylactoid Reactions

Allergic reactions, including severe anaphylactoid reactions, have been reported following the infusion of FEIBA. If signs and symptoms of severe allergic reactions occur, immediately discontinue administration of FEIBA NF and provide appropriate supportive care. Epinephrine and other appropriate medications to treat allergic reactions should be available whenever FEIBA NF is administered.

Thrombotic and Thromboembolic Events

Thrombotic and thromboembolic events [including disseminated intravascular coagulation (DIC), venous thrombosis, pulmonary embolism, myocardial infarction, and stroke] have been

reported following infusion of FEIBA VH or FEIBA NF, particularly following the administration of high doses and/or in patients with thrombotic risk factors (see *ADVERSE REACTIONS*). The possible presence of such risk factors should always be considered in patients with congenital and acquired hemophilia. Thromboembolic events are well recognized potential complications of FEIBA infusion. Many of these events occurred with doses above 200 units/kg/day or in patients with other risk factors for thromboembolic events. A single dose of 100 units/kg body weight and a daily dose of 200 units/kg body weight should not be exceeded unless the severity of bleeding warrants and justifies the use of higher doses. Patients receiving more than 100 units/kg of body weight of FEIBA NF must be monitored for the development of DIC and/or symptoms of acute coronary ischemia. High doses of FEIBA NF should be given only as long as absolutely necessary to stop bleeding.

Patients with disseminated intravascular coagulation (DIC), advanced atherosclerotic disease, crush injury, septicemia, or concomitant treatment with recombinant factor VIIa have an increased risk of developing thrombotic events due to circulating tissue factor (TF) or predisposing coagulopathy.

FEIBA NF should be used with particular caution and only if there are no therapeutic alternatives in patients:

- at risk of DIC, arterial or venous thrombosis.
- with existing thrombotic conditions (e.g., acute myocardial infarction, or venous thrombosis).

FEIBA NF should not be given to patients with significant signs of disseminated intravascular coagulation (DIC) or fibrinolysis. Infusion of FEIBA NF should not exceed single dosage of 100 units per kg of body weight and daily doses of 200 units per kg body weight. Thrombotic events have been identified through post-marketing surveillance following FEIBA use for each of the approved indications. The incidence of thrombotic events cannot be determined from post-marketing data.

Transmission of Infectious Agents

FEIBA NF (Anti-Inhibitor Coagulant Complex), nanofiltered and vapor heated, is made from human plasma. Products made from plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by effective donor screening, testing for the presence of certain current virus infections, by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly non-A, non- B hepatitis. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Baxter Healthcare Corporation, at 1-800-423-2862 (in the U.S.). The physician should discuss the risks and benefits of this product with the patient.

Anamnestic Responses

Anamnestic responses with rise in Factor VIII inhibitor titer have been observed in 20% of the cases (see *CLINICAL STUDIES*).

PRECAUTIONS

General

Caution should be used when administering FEIBA VH or FEIBA NF to patients with an increased risk of thromboembolic complications. These include, but are not limited to, patients with a history of coronary heart disease, liver disease, disseminated intravascular coagulation, post-operative immobilization, elderly patients and neonates. In each of these situations, the potential benefit of treatment with FEIBA VH or FEIBA NF should be weighed against the risk of these complications.

Patients who receive FEIBA VH or FEIBA NF should be monitored for development of signs or symptoms of DIC, acute coronary ischemia, and signs and symptoms of other thrombotic and thromboembolic events. If clinical signs of intravascular coagulation occur, which include changes in blood pressure, changes in pulse rate, respiratory distress, chest pain and/or cough, the infusion should be stopped promptly and appropriate diagnostic and therapeutic measures are to be initiated.

Laboratory indications of DIC are decreased fibrinogen, decreased platelet count, and/or presence of fibrin-fibrinogen degradation products (FDP). Other indications of DIC include significantly prolonged thrombin time, prothrombin time, or partial thromboplastin time.

It has been reported that FEIBA NF and antifibrinolytics have been given simultaneously without complications. No adequate and well-controlled studies of the combined or sequential use of FEIBA NF and recombinate Factor VIIa or antifibrinolytics have been conducted. The possibility of thrombotic events should be considered when systemic antifibrinolytics such as tranexamic acid and aminocaproic acid are used during treatment with FEIBA NF. It is recommended not to use antifibrinolytics until 12 hours after the administration of FEIBA NF.

Information for Patients

Some viruses, such as parvovirus B19 or hepatitis A, are particularly difficult to remove or inactivate at this time. Parvovirus B19 most seriously affects pregnant women or immune-compromised individuals. Symptoms of parvovirus B19 infection include fever, drowsiness, chills, and runny nose followed about two weeks later by a rash, and joint pain. Evidence of hepatitis A may include several days to weeks of poor appetite, tiredness, and low-grade fever followed by nausea, vomiting, and pain in the belly. Dark urine and a yellowed complexion are also common symptoms. Patients should be encouraged to consult their physician if such symptoms appear.

Non-Hemophilic Patients

Non-hemophilic patients with acquired inhibitors against Factors VIII, IX or XII may have both a bleeding tendency and an increased risk of thrombosis at the same time.

Laboratory Tests and Clinical Efficacy

Tests used to help evaluate hemostasis, such as APTT, WBCT, and TEG do not correlate with clinical improvement. For this reason, attempts at normalizing these values by increasing the dose of FEIBA NF may not be successful and are strongly discouraged because of the potential hazard of producing DIC by overdose.

Pregnancy Category C

Animal reproduction studies have not been conducted with FEIBA NF. It is also not known whether FEIBA NF can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. FEIBA NF should be given to a pregnant woman only if clearly needed.

Pediatric Use

No data are available regarding the use of FEIBA NF in newborns.

ADVERSE REACTIONS

The following adverse reactions have been identified during post approval use of FEIBA: Myocardial infarction, disseminated intravascular coagulopathy, injection site pain, anaphylactic reaction, hypersensitivity, urticaria, blood pressure decreased, hypoaesthesia, hypoaesthesia facial, and embolism.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

OVERDOSAGE

Overdosage of FEIBA NF may increase the risk of thromboembolism, DIC or myocardial infarction (see *WARNINGS*).

DOSAGE AND ADMINISTRATION

(See under *Intravenous Injection or Infusion:*).

Clinical trials[1,2] demonstrated that the response to treatment with FEIBA may differ from patient to patient with no correlation to the patient's inhibitor titer. Response may also vary between different types of hemorrhage (e.g. joint hemorrhage vs. CNS hemorrhage). As a general guideline, a dosage range of 50 to 100 Units of FEIBA NF per kg of body weight is recommended. However, care should be taken to distinguish between the following four indications, all of which have undergone careful clinical evaluation:

Joint Hemorrhage

In joint hemorrhage, a dose of 50 units per kg of body weight is recommended at 12-hour intervals, which may be increased to doses of 100 units per kg of body weight at 12-hour intervals.

Treatment should be continued until clear signs of clinical improvement appear, such as relief of pain, reduction of swelling or mobilization of the joint.

Mucous Membrane Bleeding

A dose of 50 units per kg of body weight is recommended to be given at 6-hour intervals under careful monitoring (visible bleeding site, repeated measurements of the patient's hematocrit). If hemorrhage does not stop, the dose may be increased to 100 units per kg of body weight at 6-hour intervals. Two such administrations or 200 units per kg of body weight a day should not be exceeded.

Soft Tissue Hemorrhage

For serious soft tissue bleeding, such as retroperitoneal bleeding, doses of 100 units per kg of body weight at 12-hour intervals are recommended. A daily dosage of 200 units per kg of body weight should not be exceeded.

Other Severe Hemorrhages

Severe hemorrhages, such as CNS bleedings have been effectively treated with doses of 100 units per kg of body weight at 12-hour intervals. Sometimes, FEIBA NF may be indicated at 6-hour intervals until clear clinical improvement is achieved.

Reconstitution:

1. Allow the unopened vials of FEIBA NF (concentrate) and Sterile Water for Injection (diluent) to reach room temperature (not above 37ºC, 98ºF).
2. Remove the caps from the concentrate and diluent vials to expose central portions of the rubber stoppers.
3. Disinfect the rubber stoppers of both vials using a germicidal solution. Place the vials on an even surface and allow them to dry.
4. Open the package of the BAXJECT II Hi-Flow device by peeling away the lid without touching the inside contents (Fig. A). **Do not remove the transfer system from the package**. Do not touch the clear spike.
5. (Fig. B).
6. Grip the BAXJECT II Hi-Flow device package at the edges and pull the package off the device (Fig. C). **Do not remove** the blue protective cap from the BAXJECT II Hi-Flow device. Do not

touch the purple spike.

7. Turn the system over so that the vial is on top. Press the purple spike of the BAXJECT II Hi-Flow device fully into the FEIBA NF vial. The vacuum will draw the diluent into the FEIBA NF vial (Fig. D).
8. Swirl the entire system gently until the powder is dissolved. Make sure that the FEIBA NF has been dissolved completely.

Fig A

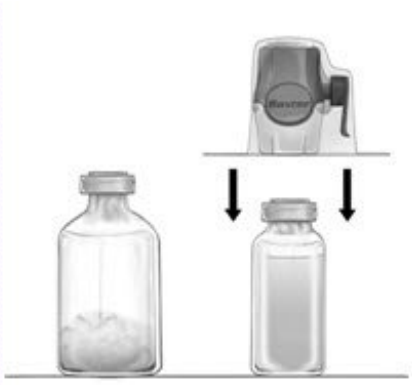

Fig B

Fig C

Fig D

Do not refrigerate after reconstitution!

After complete reconstitution of FEIBA NF, its injection or infusion should be commenced as promptly as practicable, but must be completed within three hours following reconstitution. The solution must be given by intravenous injection or intravenous drip infusion.

Intravenous Injection/Infusion:

Inspect for particulate matter and discoloration after reconstituting the concentrate as described under **Reconstitution** prior to administration. The appearance of the solution should be colorless to slightly yellowish and essentially free of visible particles.

Plastic Luer lock syringes are recommended for use with this product since protein such as FEIBA NF tends to stick to the surface of all-glass syringes.

1. Remove the blue protective cap from the BAXJECT II Hi-Flow device. Connect the syringe to the BAXJECT II Hi-Flow device (DO NOT DRAW AIR INTO THE SYRINGE) (Fig. E).
2. (Fig. F).
3. Disconnect the syringe, attach a suitable needle and inject or infuse intravenously as instructed under *Rate of Administration*.

Fig E

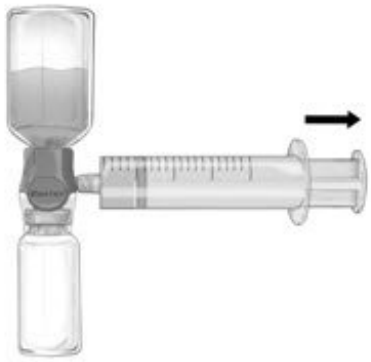

Fig F

Rate of Administration:

The **maximum injection or infusion rate must not exceed 2 units per kg of body weight per minute.** For a patient with a body weight of 75 kg, this corresponds to an infusion rate of 2.5-7.5 mL per minute depending on the number of units per vial (see label on vial).

HOW SUPPLIED

FEIBA NF is available in single-dose vials in the following nominal dosage strengths:

Blue - 500 Units per vial (NDC 64193-423-02)

Green - 1000 Units per vial (NDC 64193-424-02)

Purple - 2500 Units per vial (NDC 64193-425-02)

The number of Units of Factor VIII inhibitor bypassing activity is stated on the label of each vial.

FEIBA NF is packaged with a suitable volume (20 mL or 50 mL) of Sterile Water for Injection, U.S.P., one BAXJECT II Hi-Flow Needleless Transfer Device, and one Package Insert.

Certain components of the packaging material contain Dry Natural Rubber Latex.

STORAGE

Store at refrigerated temperature (2° to 8°C, 35° to 46°F). Within the indicated shelf life, the product may be stored at room temperature (not exceeding 25°C, 77°F) for up to 6 months.

After storage at room temperature, the product must not be returned to the refrigerator.

Please note: If you transfer the product from the refrigerator to room temperature, it expires at the end of the 6 months period or at the end of shelf life, whatever comes earlier.

Record the date on the package prior to shifting the product at room temperature.

Avoid freezing, which may damage the diluent vial.

REFERENCES

1. Sjamsoedin L. J. M., Heijnen L., Mauser-Bunschoten E. P., van Geijlswijk J. L., van Houwelingen H., van Asten P., Sixma J. J.: The Effect of Activated Prothrombin-Complex Concentrate (FEIBA) on Joint and Muscle Bleeding in Patients with Hemophilia A and Antibodies to Factor VIII. The New Engl. J. of Med. 305: 717, 1981.
2. Hilgartner M. W., Knatterud G. AND THE FEIBA STUDY GROUP: The Use of Factor-Eight-

Inhibitor-By-Passing-Activity (FEIBA IMMUNO) Product for Treatment of Bleeding Episodes in Hemophiliacs with Inhibitors. Blood 61: 36, 1983.
3. Vermylen J., Schetz J., Semeraro N., Mertens F., Verstraete M.: Evidence that 'Activated' Prothrombin Concentrates Enhance Platelet Coagulant Activity. Brit. J. Haematol. 38: 235, 1978.
4. Semeraro N., Vermylen J.: Evidence that Washed Human Platelets Possess Factor-X Activator Activity. Brit. J. Haematol. 36: 107, 1977.
5. Wensley R. T.: General Summary of the Use of FEIBA in Haemophiliacs with Inhibitors to FVIII. Presentation at the Second Workshop on Factor VIII Inhibitor Patients, Vienna, 1979.

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Call 1-888-UPDATE U(1-888-873-2838).

Baxter Healthcare Corporation

Westlake Village, CA 91362 USA

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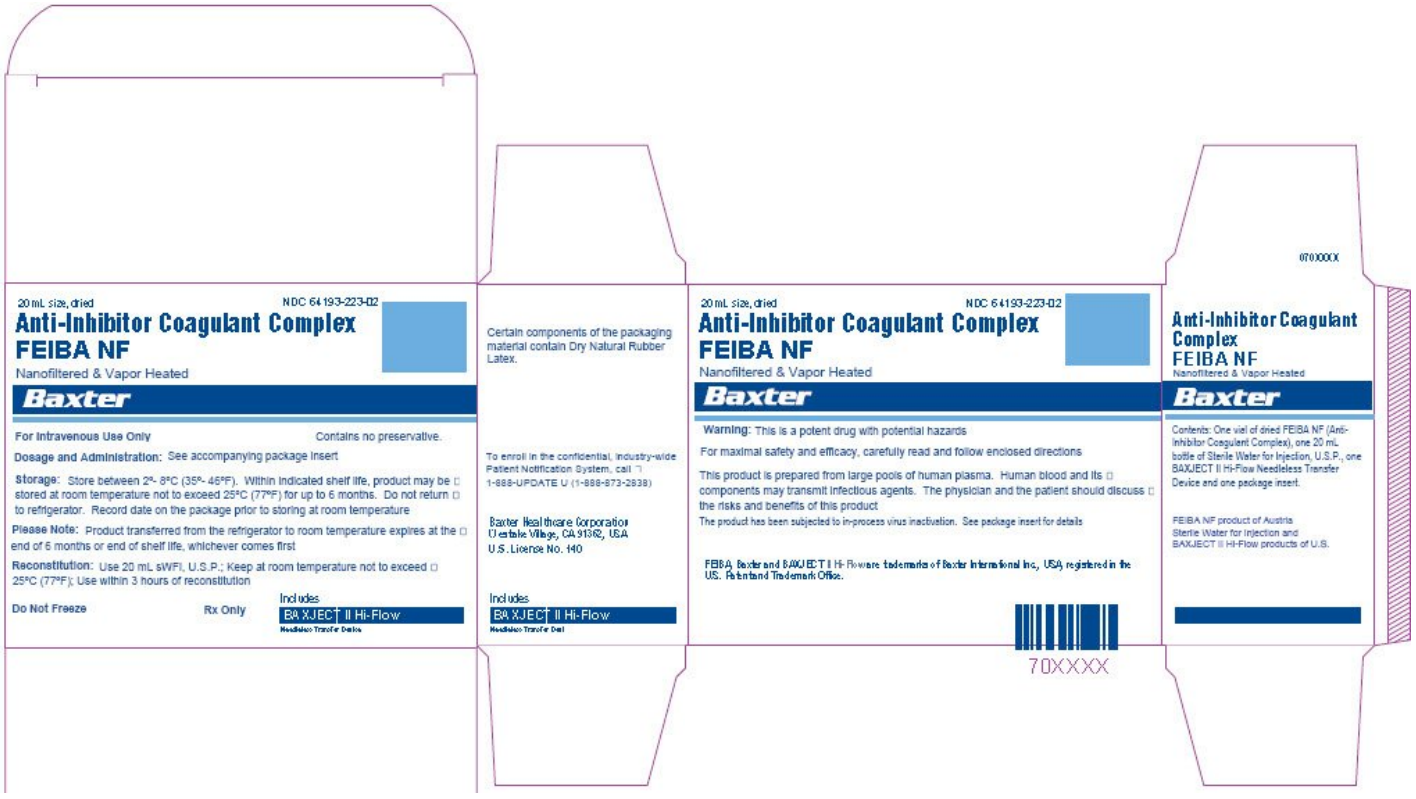
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



FEIBA NF 500 U unit carton

20 mL size, dried

NDC 64193-423-02

Anti-Inhibitor Coagulant Complex

FEIBA NF

Nanofiltered & Vapor Heated

Baxter

For Intravenous Use Only

Contains no preservative.

Dosage and Administration: See accompanying package insert

Storage: Store between 2º -8ºC (35º-46ºF). Within indicated shelf life, product may be stored at room temperature not to exceed 25ºC (77ºF) for up to 6 months. Do not return to refrigerator. Recode date on the package prior to storing at room temperature

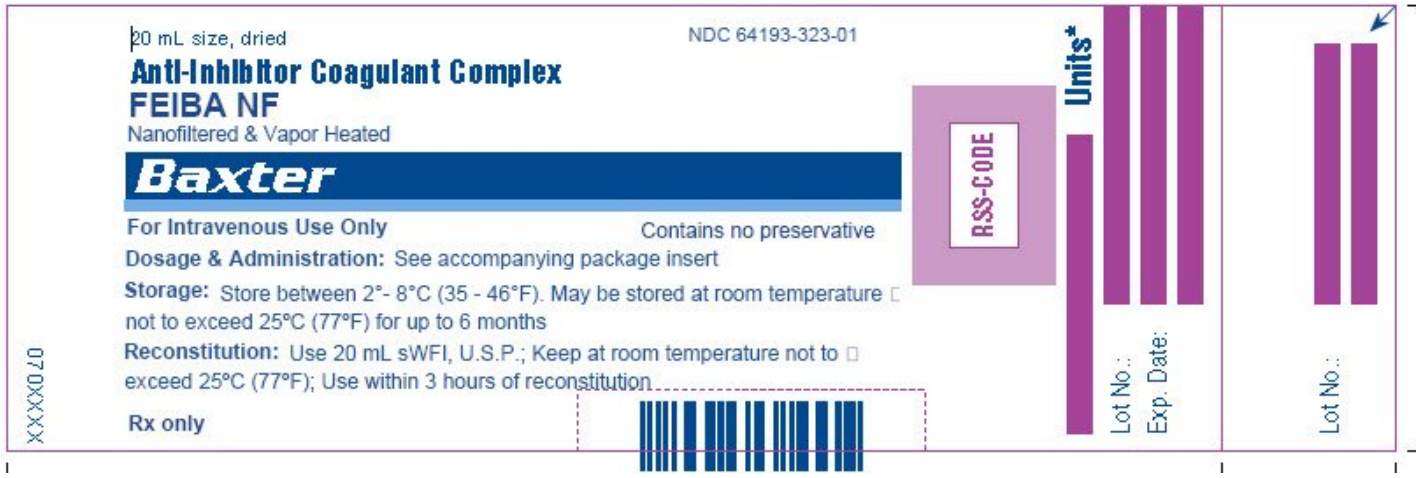
Please Note: Product transferred from the refrigerator to room temperature expires at the end of 6 months or end of shelf life, whichever comes first

Reconstitution: Use 20 mL sWFI, U.S.P.; Keep at room temperature not to exceed 25ºC (77ºF); Use within 3 hours of reconstitution

Do Not Freeze

Rx Only

Includes BAXJECT II Hi-Flow Needleless Transfer Device



FEIBA NF 500 U vial label

20 mL size, dried

NDC 64193-323-01

Anti-Inhibitor Coagulant Complex

FEIBA NF

Nanofiltered & Vapor Heated

For Intravenous Use Only

Contains no preservative.

Dosage and Administration: See accompanying package insert

Storage: Store between 2º -8ºC (35º-46ºF). Within indicated shelf life, product may be stored at room temperature not to exceed 25ºC (77ºF) for up to 6 months.

Reconstitution: Use 20 mL sWFI, U.S.P.; Keep at room temperature not to exceed 25ºC (77ºF); Use

within 3 hours of reconstitution

Rx Only

20 mL Sterile Water for Injection

1A7141

NDC 0338-0764-62

20 mL Single-Dose Container Nonpyrogenic

Sterile Water for Injection, USP for reconstitution of accompanying product

Do not use unless clear. No antimicrobial agent of other substance has been added. Do not use for intravascular injection without making approximately isotonic by addition of suitable solute. Discard unused portion. Rx Only. This Product Contains Dry Natural Rubber.

Baxter

Manufactured by

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

FEIBA NF

anti-inhibitor coagulant complex kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64193-423

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64193-423-02	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	25 mL
Part 2	1 VIAL, GLASS	20 mL

Part 1 of 2

FEIBA NF

anti-inhibitor coagulant complex injection, powder, lyophilized, for solution

Product Information

Route of Administration	INTRAVENOUS	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ANTI-INHIBITOR COAGULANT COMPLEX (UNII: CS849DUN3M) (ANTI-INHIBITOR COAGULANT COMPLEX - UNII:CS849DUN3M)	ANTI-INHIBITOR COAGULANT COMPLEX	25 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		25 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

Part 2 of 2

STERILE WATER FOR INJECTION

water liquid

Product Information

Route of Administration	INTRAVENOUS	DEA Schedule	

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	20 mL in 20 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		20 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

FEIBA NF

anti-inhibitor coagulant complex kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64193-424

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64193-424-02	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	50 mL
Part 2	1 VIAL, GLASS	20 mL

Part 1 of 2

FEIBA NF

anti-inhibitor coagulant complex injection, powder, lyophilized, for solution

Product Information			
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ANTI-INHIBITOR COAGULANT COMPLEX (UNII: CS849DUN3M) (ANTI-INHIBITOR COAGULANT COMPLEX - UNII:CS849DUN3M)	ANTI-INHIBITOR COAGULANT COMPLEX	50 [USP'U] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

Part 2 of 2

STERILE WATER FOR INJECTION

water liquid

Product Information			
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	20 mL in 20 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1		1 in 1 CARTON		
1		20 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

FEIBA NF

anti-inhibitor coagulant complex kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64193-425

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64193-425-02	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	50 mL
Part 2	1 VIAL, GLASS	50 mL

Part 1 of 2

FEIBA NF

anti-inhibitor coagulant complex injection, powder, lyophilized, for solution

Product Information

Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ANTI-INHIBITOR COAGULANT COMPLEX (UNII: CS849DUN3M) (ANTI-INHIBITOR COAGULANT COMPLEX - UNII:CS849DUN3M)	ANTI-INHIBITOR COAGULANT COMPLEX	50 [USP'U] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA101447	07/01/2011	

Part 2 of 2

STERILE WATER FOR INJECTION

water liquid

Product Information			
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	50 mL in 50 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		50 mL in 1 VIAL, GLASS		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA101447	07/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101447	07/01/2011	

Labeler - Baxter Healthcare Corporation (085206634)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Innovations GmbH		300178716	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		001728059	MANUFACTURE, LABEL

Revised: 7/2010 Baxter Healthcare Corporation